



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-1005]

Safety Considerations for Product Design to Minimize Medication Errors; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a guidance for industry entitled "Safety Considerations for Product Design to Minimize Medication Errors." The guidance is intended for sponsors of investigational new drug applications (INDs); applicants of new drug applications (NDAs), biologics licensing applications (BLAs), and abbreviated new drug applications (ANDAs); and manufacturers of prescription drugs marketed without an approved application or over-the-counter (OTC) monograph drugs. This guidance provides sponsors, applicants, and manufacturers with a set of principles to consider while developing drug products using a systems approach to minimize medication errors relating to product design and container closure design. The recommendations in this guidance document are intended to provide best practices on how to improve the drug product and container closure design for all prescription and nonprescription drug products. This guidance also provides examples of product designs that resulted in postmarketing error.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2012-D-1005 for "Safety Considerations for Product Design to Minimize Medication Errors." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document. FOR FURTHER INFORMATION CONTACT: Irene Z. Chan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4420, Silver Spring, MD 20993-0002, 301-796-3962.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Safety Considerations for Product Design to Minimize Medication Errors." The guidance is intended for sponsors of INDs; applicants of NDAs, BLAs, and ANDAs; and manufacturers of prescription drugs marketed without an approved application or OTC monograph drugs. This guidance provides sponsors, applicants, and manufacturers with a set of principles to consider while developing drug products using a systems approach to minimize medication errors relating to product design and container closure design. The recommendations in this guidance document are intended to provide best practices on how to improve the drug product and

container closure design for all prescription and nonprescription drug products. The guidance also provides examples of product designs that resulted in postmarketing error.

This guidance document, which focuses on minimizing risks associated with the design of the drug product and its container closure system, is the first in a series of three planned guidances to minimize or eliminate hazards contributing to medication errors. The second guidance focuses on minimizing risks with the design of drug product container labels and carton labeling. The third guidance focuses on minimizing risks when developing and selecting proposed proprietary names for drugs.

In the **Federal Register** of December 13, 2012 (77 FR 74196), FDA announced the availability of the draft guidance entitled "Safety Considerations for Product Design to Minimize Medication Errors." The Agency has carefully reviewed and considered the comments it received in developing this final version of the guidance. The Agency has made revisions to the guidance to address public comments requesting clarifications and implement formatting changes for improved readability as it deemed appropriate. The Agency also moved recommendations appropriate for labels and labeling to a separate guidance. The guidance announced in this notice finalizes the draft guidance dated December 2012.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on addressing safety achieved through drug product design to minimize medication errors. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910-0014. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910-0001. The collections of information in 21 CFR part 601 have been approved under OMB control number 0910-0338.

IV. Electronic Access

You may obtain the document at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: April 6, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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